

1 ACCOMMODATING INTRAOCULAR LENS

## 2

## 3 BACKGROUND OF THE INVENTION

## 5 1. Field of the Invention

6 This invention relates broadly to ophthalmic implants. More  
7 particularly, this invention relates to intraocular lenses which  
8 are focusable and allow for accommodation for near vision.

## 0 2. State of the Art

11 Referring to Fig. 1, the human eye 10 generally comprises a  
12 cornea 12, an iris 14, a ciliary body (muscle) 16, a capsular bag  
13 18 having an anterior wall 20 and a posterior wall 22, and a  
14 natural crystalline lens 24 contained within the walls of the  
15 capsular bag. The capsular bag 18 is connected to the ciliary  
16 body 16 by means of a plurality of zonules 26 which are strands or  
17 fibers. The ciliary body 16 surrounds the capsular bag 18 and  
18 lens 24, defining an open space, the diameter of which depends  
19 upon the state (relaxed or contracted) of the ciliary body 16.

When the ciliary body 16 relaxes, the diameter of the opening increases, and the zonules 26 are pulled taut and exert a tensile force on the anterior and posterior walls 20, 22 of the capsular bag 18, tending to flatten it. As a consequence, the lens 24 is also flattened, thereby undergoing a decrease in focusing power.

1 This is the condition for normal distance viewing. Thus, the  
2 emmetropic human eye is naturally focussed on distant objects.

3

4 Through a process termed accommodation, the human eye can  
5 increase its focusing power and bring into focus objects at near.

6 Accommodation is enabled by a change in shape of the lens 24.

7 More particularly, when the ciliary body 16 contracts, the  
8 diameter of the opening is decreased thereby causing a  
9 compensatory relaxation of the zonules 26. This in turn removes  
10 or decreases the tension on the capsular bag 18, and allows the  
11 lens 24 to assume a more rounded or spherical shape. This rounded  
12 shape increases the focal power of the lens such that the lens  
13 focuses on objects at near.

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15 As such, the process of accommodation is made more efficient  
16 by the interplay between stresses in the ciliary body and the  
17 lens. When the ciliary body relaxes and reduces its internal  
18 stress, there is a compensatory transfer of this stress into the  
19 body of the lens, which is then stretched away from its globular  
20 relaxed state into a more stressed elongated conformation for  
21 distance viewing. The opposite happens as accommodation occurs  
22 for near vision, where the stress is transferred from the  
23 elongated lens into the contracted ciliary body.

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1       In this sense, referring to Fig. 2, there is conservation of  
2 potential energy (as measured by the stress or level of  
3 excitation) between the ciliary body and the crystalline lens from  
4 the point of complete ciliary body relaxation for distance vision  
5 through a continuum of states leading to full accommodation of the  
6 lens.

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8       As humans age, there is a general loss of ability to  
9 accommodate, termed "presbyopia", which eventually leaves the  
10 person unable to focus on near objects. In addition, when  
11 cataract surgery is performed and the natural crystalline lens is  
12 replaced by an artificial intraocular lens, there is generally a  
13 complete loss of the ability to accommodate. This occurs because  
14 the active muscular process of accommodation involving the ciliary  
15 body is not translated into a change in focusing power of the  
16 implanted artificial intraocular lens.

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18       There have been numerous attempts to achieve at least some  
19 useful degree of accommodation with an implanted intraocular lens  
20 which, for various reasons, fall short of being satisfactory. In  
21 U.S. Pat. No. 4,666,446 to Koziol et al., there is shown an  
22 intraocular lens having a complex shape for achieving a bi-focal  
23 result. The lens is held in place within the eye by haptics which  
24 are attached to the ciliary body. However, the implant requires  
25 the patient to wear spectacles for proper functioning. Another

1 device shown in U.S. Pat. No. 4,944,082 to Richards et al., also  
2 utilizes a lens having regions of different focus, or a pair of  
3 compound lenses, which are held in place by haptics attached to  
4 the ciliary body. In this arrangement, contraction and relaxation  
5 of the ciliary muscle causes the haptics to move the lens or  
6 lenses, thereby altering the effective focal length. There are  
7 numerous other patented arrangements which utilize haptics  
8 connected to the ciliary body, or are otherwise coupled thereto,  
9 such as are shown in U.S. Pat. Nos. 4,932,966 to Christie et al.,  
10 U.S. Pat. No. 4,888,012 to Horne et al. and U.S. Pat. No.  
11 4,892,543 to Turley, and rely upon the ciliary muscle to achieve  
12 the desired alteration in lens focus.

13

14 In any arrangement that is connected to the ciliary body, by  
15 haptic connection or otherwise, extensive erosion, scarring, and  
16 distortion of the ciliary body usually results. Such scarring and  
17 distortion leads to a disruption of the local architecture of the  
18 ciliary body and thus causes failure of the small forces to be  
19 transmitted to the intraocular lens. Thus, for a successful long-  
20 term implant, connection and fixation to the ciliary body is to be  
21 avoided if at all possible.

22

23 In U.S. Pat. No. 4,842,601 to Smith, there is shown an  
24 accommodating intraocular lens that is implanted into and floats  
25 within the capsular bag. The lens comprises front and rear

1 flexible walls joined at their edges, which bear against the  
2 anterior and posterior inner surfaces of the capsular bag. Thus,  
3 when the zonules exert a tensional pull on the circumference of  
4 the capsular bag, the bag, and hence the intraocular lens, is  
5 flattened, thereby changing the effective power of refraction of  
6 the lens. The implantation procedure requires that the capsular  
7 bag be intact and undamaged and that the lens itself be  
8 dimensioned to remain in place within the bag without attachment  
9 thereto. Additionally, the lens must be assembled within the  
10 capsular bag and biasing means for imparting an initial shape to  
11 the lens must be activated within the capsular bag. Such an  
12 implantation is technically quite difficult and risks damaging the  
13 capsular bag, inasmuch as most of the operations involved take  
14 place with tools which invade the bag. In addition, the Smith  
15 arrangement relies upon pressure from the anterior and posterior  
16 walls of the capsular bag to deform the lens, which requires that  
17 the lens be extremely resilient and deformable. However, the more  
18 resilient and soft the lens elements, the more difficult assembly  
19 within the capsular bag becomes. Furthermore, fibrosis and  
20 stiffening of the capsular remnants following cataract surgery may  
21 make this approach problematic.

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23 U.S. Patent 6,197,059 to Cumming and U.S. Patent 6,231,603 to  
24 Lang each disclose an intraocular lens design where the  
25 configuration of a hinged lens support ostensibly allows the

1 intraocular lens to change position in response to accommodation  
2 and thus change effective optical power. U.S. Patent 6,299,641 to  
3 Woods describes another intraocular lens that also increases  
4 effective focusing power as a result of a change in axial position  
5 during accommodation. In each of these intraocular lenses, a  
6 shift in axial position and an increase in distance from the  
7 retina results in a relative increase in focusing power. All  
8 lenses that depend upon a shift in the position of the lens to  
9 achieve some degree of accommodation are limited by the amount of  
10 excursion possible during accommodation.

11

12 U.S. Patent 5,607,472 to Thompson describes a dual-lens  
13 design. Prior to implantation, the lens is stressed into a non-  
14 accommodative state with a gel forced into a circumferential  
15 expansion channel about the lens. At implantation, the surgeon  
16 must create a substantially perfectly round capsulorrhesis, and  
17 insert the lens therethrough. A ledge adjacent to the anterior  
18 flexible lens is then bonded 360° around (at the opening of the  
19 capsulorrhesis) by the surgeon to the anterior capsule to secure  
20 the lens in place. This approach has numerous drawbacks, a few of  
21 which follow. First, several aspects of the procedure are  
22 substantially difficult and not within the technical skill level  
23 of many eye surgeons. For example, creation of the desired round  
24 capsulorrhesis within the stated tolerance required is  
25 particularly difficult. Second, the bonding "ledge" may disrupt

1 the optical image produced by the adjacent optic. Third,  
2 intraocular bonding requires a high degree of skill, and may fail  
3 if the capsulorrhesis is not 360° round. Fourth, the proposed  
4 method invites cautionary speculation as to the result should the  
5 glue fail to hold the lens in position in entirety or over a  
6 sectional region. Fifth, it is well known that after lens  
7 implantation surgery the capsular bag, upon healing, shrinks.  
8 Such shrinking can distort a lens glued to the bag in a pre-shrunk  
9 state, especially since the lens is permanently affixed to a  
10 structure which is not yet in equilibrium. Sixth, Thompson fails  
11 to provide a teaching as to how or when to release the gel from  
12 the expansion channel; i.e., remove the stress from the lens. If  
13 the gel is not removed, the lens will not accommodate. If the gel  
14 is removed during the procedure, the lens is only in a flattened  
15 non-accommodating shape during adhesion to the capsule, but not  
16 post-operatively, and it is believed that the lens therefore will  
17 fail to interact with the ciliary body as required to provide the  
18 desired accommodation as the capsular bag may change shape in the  
19 post-operative period. If the gel is otherwise removed  
20 thereafter, Thompson ostensibly requires an additional surgical  
21 procedure therefor. In view of these problems, it is doubtful  
22 that the lens system disclosed by Thompson can be successfully  
23 employed.  
24

1        Thus, the prior art discloses numerous concepts for  
2    accommodating intraocular lenses. However, none are capable of  
3    providing an accommodating implant which does not, in one way or  
4    another, risk damage to the ciliary body or the capsular bag,  
5    present technical barriers, or present potential serious  
6    consequences upon failure of the device.

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## SUMMARY OF THE INVENTION

10 It is therefore an object of the invention to provide an  
11 intraocular lens that functions similarly to the natural  
12 crystalline lens.

4 It is another object of the invention to provide an  
5 intraocular lens that changes shape and increases power during  
6 accommodation.

7

8 It is also an object of the invention to provide an  
9 intraocular lens that produces a sufficient increase in focusing  
10 power such that it is clinically useful.

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22 It is an additional object of the invention to provide an  
23 intraocular lens that permits uncomplicated implantation of the  
24 lens in a manner compatible with modern-day cataract surgery  
25 techniques.

1        In accord with these objects, which will be discussed in  
2 detail below, an intraocular lens (IOL) system that permits  
3 accommodation and a method of implanting such an intraocular lens  
4 system are provided. According to one embodiment of the  
5 invention, the intraocular lens system includes a flexible optic  
6 having a skirt (periphery or haptic), and a restraining element  
7 about the skirt and adapted to temporarily maintain the flexible  
8 optic in a stressed, non-accommodating configuration during a  
9 post-operative period. The restraining element may comprise a  
10 dissolvable bioabsorbable material such that the element  
11 automatically releases the optic after a post-operative period, or  
12 may be released under the control of a eye surgeon, preferably via  
13 a non-surgically invasive means such as via a laser or a chemical  
14 agent added to the eye.

15  
16        According to a preferred method of implantation, the ciliary  
17 body muscle is pharmacologically induced into a relaxed stated  
18 (cycloplegia), a capsulorrhesis is performed on the lens capsule,  
19 and the natural lens is removed from the capsule. The prosthetic  
20 lens is then placed within the lens capsule. According to a  
21 preferred aspect of the invention, the ciliary body is maintained  
22 in the relaxed state for the duration of the time required for the  
23 capsule to naturally heal and shrink about the lens; i.e.,  
24 possibly for several weeks. After healing has occurred, the  
25 restraining element automatically or under surgeon control

1 releases the optic from the stressed state. The ciliary body and  
2 lens may then interact in a manner substantially similar to the  
3 physiological interaction between the ciliary body and a healthy  
4 natural crystalline lens.

5

6 Alternatively, a fully relaxed lens (i.e., without  
7 restraining element) can be coupled to a fully stressed and  
8 contracted ciliary body.

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11 The intraocular lens system of the invention is compatible  
12 with modern cataract surgery techniques and allows for large  
13 increases in optical power of the implanted lens. Unlike other  
14 proposed accommodating intraocular lens systems, the lens  
15 described herein is capable of higher levels of accommodation and  
16 better mimics the function of the lens of the human eye. Further,  
17 unlike other lens systems previously described, the lens take into  
18 account certain reciprocal aspects of the relationship between the  
19 natural crystalline lens and the ciliary body. Moreover, the  
20 implantation is relatively easy and rapid.

21

22 Additional objects and advantages of the invention will  
23 become apparent to those skilled in the art upon reference to the  
24 detailed description taken in conjunction with the provided  
25 figures.

1                   BRIEF DESCRIPTION OF THE DRAWINGS  
23               Fig. 1 is a diagrammatic view of a cross-section of a normal  
4       eye;5  
6               Fig. 2 is a graph of the stresses on the ciliary body-  
7       crystalline lens system of the eye in a continuum of states  
8       between distance vision and full accommodation;9  
10              Fig. 3 is a schematic front view of an intraocular lens  
11       according to the invention configured into a stressed state with a  
12       restraining element;13  
14              Fig. 4 is a schematic transverse section view of the  
15       intraocular lens of Fig. 3 in a stressed state;16  
17              Fig. 5 is a schematic transverse section view of the  
18       intraocular lens of Fig. 3 in a non-stressed accommodating state;19  
20              Figs. 6 and 7 are other schematic transverse section views of  
21       intraocular lenses according to the invention;22  
23              Fig. 8 is a schematic front view of an intraocular lens  
24       according to the invention with the restraining element removed,  
25       and thus, configured in a non-stressed accommodating state;

1       Fig. 9 is a transparent front view of an intraocular lens  
2   according to the invention shown with a second embodiment of a  
3   restraining element;

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5       Fig. 10 is a schematic transverse view of the intraocular  
6   lens of Fig. 9;

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8       Fig. 11 is a transparent front view of an intraocular lens  
9   according to the invention shown with a third embodiment of a  
10   restraining element;

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12       Fig. 12 is a schematic transverse view of the intraocular  
13   lens of Fig. 11;

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15       Fig. 13 is a transparent front view of an intraocular lens  
16   according to the invention shown with a third embodiment of a  
17   restraining element;

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19       Fig. 14 is a schematic transverse view of the intraocular  
20   lens of Fig. 13;

21

22       Fig. 15 is a schematic front view of an intraocular lens  
23   according to the invention having a particular skirt configuration  
24   which include haptics and another alternate embodiment restraining  
25   element;

1       Fig 16 is a schematic front view of another intraocular lens  
2 according to the invention having a particular skirt configuration  
3 which include haptics and yet another alternate embodiment  
4 restraining element;

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6       Fig. 17 is a schematic side view of the intraocular lens of  
7 Fig. 16;

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Fig. 18 is an intraocular lens according to the invention  
having a particular skirt configuration which include haptics and  
yet a further alternate embodiment restraining element;

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Fig. 19 is a block diagram of a first embodiment of a method  
of implanting an intraocular lens according to the invention;

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Fig. 20 is a block diagram of a second embodiment of a method  
of implanting an intraocular lens according to the invention; and

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Fig. 21 is a block diagram of a third embodiment of a method  
of implanting an intraocular lens according to the invention.

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#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

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1 lens includes a pliable optic portion 102 having an elastic  
2 memory, and is peripherally surrounded by a skirt portion 104. A  
3 restraining element 106 is provided on the skirt portion 104 and  
4 operates to hold the skirt portion and optic portion 102 in a  
5 stressed (i.e., stretched) configuration. Comparing Fig. 3,  
6 showing the optic portion in a stressed configuration, with Fig.  
7, showing the optic portion in a non-stressed configuration, it  
8 is seen that the optic portion has a smaller diameter in the non-  
9 stressed configuration.

10  
11 More particularly, the optic portion 102 is typically  
12 approximately 5 to 6 mm in diameter and made from a silicone  
13 polymer or other suitable flexible polymer. The optic portion  
14 defines an anterior surface 110 and a posterior surface 112. The  
15 optic portion may have a biconvex shape in which each of the  
16 anterior surface 110 and posterior surface 112 have similar  
17 rounded shapes. Fig. 4 illustrates such a lens in a stressed non-  
18 accommodating configuration, while Fig. 5 illustrates such a lens  
19 in the non-stressed accommodating configuration. Alternatively,  
20 referring to Fig. 6, the anterior surface 110a may be provided  
21 with a substantially greater curvature than the posterior surface  
22 112a. In addition, referring to Fig. 7, the anterior and  
23 posterior surfaces 110, 112 of the optic portion can be evenly  
24 pliable throughout, or, referring back to Fig. 6, greater  
25 flexibility and pliability can be fashioned into the central

1 portion 114 of the anterior 110 surface of the lens to enhance the  
2 accommodating effect. This may be done by using materials of  
3 differing modulus of elasticity or by altering the thickness of  
4 the central portion and/or anterior surface 110 of the optic  
5 portion 102.

6

7 Referring back to Fig. 3, the skirt portion 104 has  
8 substantially less pliability than the optic portion 102. The  
9 periphery 116 of the skirt portion 104 is preferably provided with  
10 a plurality of circumferentially displaced fenestration holes 118.  
11 The fenestration holes 118 operate to promote firm attachment of  
12 the capsular bag to the lens skirt 104 during the healing period.  
13 That is, during the healing process, the capsular bag shrinks by a  
14 substantial amount and portions of the anterior and posterior  
15 capsular bag enter into the fenestration holes 118 and join  
16 together to lock the lens 100 within the capsule without  
17 necessitating any bonding agent, sutures, or the like.

18 Alternatively, the peripheral portion <sup>All</sup>104 could be fashioned with  
19 a textured surface, ridges or any surface modification that  
20 promotes strong adhesion of the capsule to the lens skirt 104.

21

22 Referring to Figs. 3 and 4, according to a preferred, though  
23 not essential, aspect of the invention, a preferably thin and  
24 pliable collar 120 is positioned around the anterior surface of  
25 lens near the junction 122 (Fig. 8) of the optic portion 102 and

1 the skirt portion 104 to keep the more central portions of the  
2 anterior capsular remnant from adhering to the optic portion. The  
3 collar is preferably made from silicone or another smooth polymer.

4

5 As discussed above, the skirt portion 104 is maintained in a  
6 stressed configuration by the restraining element until the  
7 restraining element is removed. According to a preferred  
8 embodiment of the restraining element, the restraining element is  
9 a band provided on the outside of the skirt portion. The band 106  
10 is preferably comprised of a dissolvable, preferably bioabsorbable  
11 material that is adapted to preferably naturally dissolve in the  
12 fluid of the eye within a predetermined period of time after  
13 implantation. Alternatively, the dissolvable material may be  
14 selected so that it dissolves only upon the addition of a  
15 dissolving-promoting agent into the eye. Preferred dissolvable  
16 materials for the restraining band 106 include collagen, natural  
17 gut materials, glycan, polyglactin, poliglecaprone, polydioxanone,  
18 or other carbohydrate-based or protein-based absorbable material.

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20 Referring now to Figs. 9 and 10, according to a second  
21 embodiment of the restraining element 106a, the restraining  
22 element comprises a circumferential channel 130a in the skirt 104  
23 that is filled with a fluid or gel 132a. Preferably an isotonic  
24 solution such as a balanced salt solution is used. Alternatively,  
25 other suitable fluids, solution, or gels, including viscoelastics

1 can be used. The channel 130a has an outlet 134a that is blocked  
2 by a dissolvable, preferably bioabsorbable seal 136a. The filled  
3 channel 130a operates to stress the optic portion 102 into a non-  
4 accommodating configuration until the seal 136a is dissolved and  
5 the outlet 134a is thereby opened. Then, the material 132a within  
6 the channel 130a is forced out of the channel by the natural  
7 elasticity of the lens and permits the lens to move in accord with  
8 the excitation state of the ciliary body; i.e., between non-  
9 accommodative and accommodative states. Alternatively, the seal  
10 material 136a may not be naturally dissolvable within the  
11 environment of the eye, but rather is dissolvable within the  
12 presence of a chemical agent, such as an enzyme, which can be  
13 added to the eye. In such case, the eye surgeon can non-  
14 surgically control the release of the seal.

16 Turning now to Figs. 11 and 12, according to a third  
17 embodiment of the restraining element, the restraining element  
18 106b comprises a circumferential channel 130b in the skirt portion  
19 104 that is filled with a balanced salt solution or other suitable  
20 material 132b that maintains the optic portion into a non-  
21 accommodating stressed configuration. The channel 130b has an  
22 outlet tube 134b that is biased outward from the optic portion 102  
23 but which is preferably anchored with an anchor 135b toward the  
24 optic portion 102 but which preferably does not overlie a central  
25 area of the optic portion which would interrupt the vision of the

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1 patient when the lens is implanted. The outlet tube 134b is  
2 provided with a seal 136b made from a material, e.g., hard  
3 silicone, polymethylmethacrylate (PMMA) or plastic, that is  
4 ablative or otherwise able to be unsealed by laser light from a  
5 YAG laser or other laser suitable for eye surgery. Likewise, the  
6 anchor 135b is also made from such a material. When the lens is  
7 implanted, as discussed in detail below, the anchor 135b and the  
8 outlet tube 134b, by being directed toward the optic portion 102,  
9 is visible to the eye surgeon through a dilated iris and is  
10 positioned to receive laser light. In this embodiment, the seal  
11 136b can be removed and the outlet tube 134b opened under the full  
12 control of the eye surgeon (at his or her discretion upon post-  
13 operative evaluation of the lens recipient) by use of a laser to  
14 remove the pressure in the channel 130b to equilibrate with the  
15 anterior chamber pressure of the eye. Moreover, removal of the  
16 anchor 135b enables the outlet tube to move away from the optic  
17 portion in accord with its bias and toward the periphery to  
18 minimize any potential interference with the patient's vision.  
19

20 According to a fourth embodiment of the restraining element,  
21 any mechanical means for maintaining the lens in a stressed  
22 configuration can be used. For example, referring to Figs. 13 and  
23 14, a relatively stiff restraining element 132c having a circular  
24 form can be inserted or otherwise provided within a  
25 circumferential channel 130c. The restraining element is made

1 from a material designed to be ablated or broken upon receiving  
2 laser energy, e.g., hard silicone, polymethylmethacrylate (PMMA)  
3 or plastic. Alternatively, the end of the element 132c can be  
4 provided with a length of flexible material 134c, e.g., suture,  
5 which can be extended to outside the eye. When it is desired to  
6 remove the restraining element, the surgeon grasps the suture with  
7 a forceps and pulls the suture. This either removes the  
8 restraining element from the lens or breaks the restraining  
9 element. In either case, the stress is released from the optic.  
10 As yet another less preferred alternative, stiff restraining  
11 element is removable or broken only upon an invasive (requiring an  
12 incision) surgical procedure.

13

14 Other embodiments for the restraining elements and removal  
15 thereof are possible. For example, and not by way of limitation,  
16 the seal for an inflated channel can be attached to a suture or  
17 other length of flexible material which extends outside the eye.  
18 The suture can be pulled by the surgeon to remove the seal. In  
19 yet another example, shallow shells, adapted to be dissolvable  
20 naturally or in conjunction with an additive agent, may be  
21 provided to the front and back of the optic portion to force the  
22 optic portion to adopt a flatter (i.e., stressed) configuration.  
23 By way of another example, dissolvable or laser-removable arced  
24 struts may be provided across the lens which force the optic  
25 portion into a stressed state.

1       Moreover, embodiments of the restraining element which  
2       maintain the stressed state of the optic via external flattening  
3       of the optic or by arced struts are suitable for use with a non-  
4       circumferential skirt portion; i.e., where the skirt portion is  
5       defined by a plurality of haptics extending outward from the optic  
6       portion. For example, Figs. 15-18, illustrate the "skirt portion"  
7       defined by a plurality of haptics, rather than a complete ring  
8       about the optic. Fig. 15 discloses a skirt portion 104a defined  
9       by three haptics 140a, each of which preferably includes  
10      fenestration holes 118a. Dissolvable or laser-ablatale arced  
11      struts 142a are situated to maintain a radial stress on the optic  
12      portion 102a; i.e., the struts 142a function together as a  
13      restraining member. Figs. 16 and 17 discloses a skirt defined by  
14      four haptics 140b, each of which preferably includes fenestration  
15      holes 118b. Shells 144b are coupled to the haptics anterior and  
16      posterior of the optic to flatten the optic. Fig. 18 discloses a  
17      skirt defined by two haptics 140c, each of which preferably  
18      includes fenestration holes 118c. Multiple struts 142c are  
19      coupled to each haptic 140c.

20

21       In addition, it is recognized that the optic portion may be  
22       provided in an optically transparent bag, and the bag may be  
23       pulled or otherwise forced taught to stress the optic. The bag  
24       may be pulled taught by using one of the restraining element  
25       described above, e.g., retaining rings, channels, shells, or

1 struts, or any other suitable means, provided either directly to  
2 the bag or provided to an element coupled about a periphery of the  
3 bag.

4

5 Moreover, it is recognized that the lens of the invention may  
6 comprise two optic elements: one stationary and the other adapted  
7 to change shape and thereby alter the optic power of the dual  
8 optic system. In such an embodiment, the optic element adapted to  
9 change shape would be provided in a stressed-configuration,  
10 according to any embodiment described above.

11

12 In each embodiment of the restraining element, the  
13 restraining element is preferably configured on or in the lens  
14 during manufacture, such that the lens is manufactured, shipped,  
15 and ready for implant in a fully stressed configuration.

16

17 The lens is implanted according to a first method of  
18 implantation, as follows. Referring to Fig. 19, the patient is  
19 prepared for cataract surgery in the usual way, including full  
20 cycloplegia (paralysis of the ciliary body) at 200. Cycloplegia  
21 is preferably pharmacologically induced, e.g., through the use of  
22 short-acting anticholinergics such as tropicamide or longer-  
23 lasting anticholinergics such as atropine.

24

1        An anterior capsulorrhexis is then performed at 202 and the  
2    lens material removed. A stressed lens according to the invention  
3    is selected that preferably has an optic portion that in a  
4    stressed-state has a lens power selected to leave the patient  
5    approximately emmetropic after surgery. The lens is inserted into  
6    the empty capsular bag at 204.

7

8        Cycloplegia is maintained for several weeks (preferably two  
9    to four weeks) or long enough to allow the capsular bag to heal  
10   and "shrink-wrap" around the stressed and elongated lens at 206.  
11   This can be accomplished post-operatively through the use of one  
12   percent atropine drops twice daily. As the lens shrinks, the  
13   anterior and posterior capsular bag walls enter into the  
14   fenestration holes and join together to lock the lens in position.  
15

16        If the lens includes a restraining element having a  
17   dissolvable component, eventually the dissolvable material is lost  
18   from the lens, and the lens is unrestrained. If the lens includes  
19   a restraining element having a laser-removable component, a  
20   surgeon may at a desired time remove the component to place the  
21   lens in a unrestrained configuration. If the lens includes a  
22   restraining element which must be surgical removed or altered, the  
23   surgeon may at a desired time perform a second eye procedure to  
24   remove the component and place the lens in an unrestrained  
25   configuration.

1        Regardless of the method used, when the lens is unrestrained  
2        (i.e., released from the stressed state) at 208 and the post-  
3        operative cycloplegic medicines are stopped at 210 the lens is  
4        initially still maintained in a stressed state (Fig. 4) due to the  
5        inherent zonular stress of the non-accommodating eye. When the  
6        patient begins accommodating, the zonular stress is reduced and  
7        the implanted lens is permitted to reach a more relaxed globular  
8        conformation, as shown in Figs. 5 and 8. This change in shape  
9        provides the optic with more focusing power and thus accommodation  
10      for the patient is enabled. As with the natural crystalline lens,  
11      the relaxation of the implanted lens to a more globular shape is  
12      coupled with a development of strain or stress in the ciliary body  
13      during accommodation. Further, when the patient relaxes  
14      accommodation, the stress in the ciliary body is reduced, and  
15      there is a compensatory gain in stress as the lens is stretched  
16      into its non-accommodative shape (See again Fig. 2).

17

18        Referring to Fig. 20, according to another embodiment of the  
19        method of the invention, a lens of similar design as described  
20        above is used, except that there is no restraining element on the  
21        lens. Temporary cycloplegia is induced, and a capsulorrhesis is  
22        performed 300. The lens is implanted while the ciliary body is in  
23        a fully relaxed state at 302. The patient is then fully  
24        accommodated (i.e., the ciliary body is placed in a contracted

1 state) at 304, preferably through pharmacological agents such as  
2 pilocarpine.

3

4 Once the capsular bag is fully annealed (affixed) to the lens  
5 periphery at 306, the pharmacological agent promoting  
6 accommodation is stopped at 308. Then, as the ciliary body  
7 relaxes, the lens is stretched into an elongated shape having less  
8 focusing power. Conversely, as accommodation recurs, the lens  
9 returns to its resting shape having greater focusing power.

10

11 Referring to Fig. 21, in yet another embodiment of the method  
12 of the invention, the patient is cyclopleged during cataract  
13 surgery at 400, a capsulorrhesis is performed at 402, and a  
14 flexible lens in an unstressed state is implanted in the capsular  
15 bag at 404. After a few weeks of complete cycloplegia and during  
16 which capsular fixation of the lens periphery is accomplished at  
17 406, light (e.g., ultraviolet or infrared), a chemical agent, or  
18 another suitable means is used to shrink the optic or the adjacent  
19 skirt of the lens while the patient is still fully cyclopleged at  
20 408. In this manner, the optic is again placed into a stressed  
21 configuration while the ciliary body is fully relaxed. As with  
22 previous embodiments, when cycloplegia is stopped and  
23 accommodation occurs at 410, the lens is able to return to a more  
24 relaxed globular configuration.

25

1 There have been described and illustrated herein several  
2 embodiments of an intraocular lens and methods of implanting the  
3 same into an eye. While particular embodiments of the invention  
4 have been described, it is not intended that the invention be  
5 limited thereto, as it is intended that the invention be as broad  
6 in scope as the art will allow and that the specification be read  
7 likewise. Thus, while two particular states of intraocular lenses  
8 (fully stressed and fully accommodating) have been disclosed, it  
9 will be appreciated that there is a continuum of states of stress  
10 that can be fashioned in the inserted lens that would be  
11 appropriate for any given state of the ciliary body. In addition,  
12 while particular types of materials have been disclosed for the  
13 lens, the dissolving material, and a viscoelastic material (where  
14 used), it will be understood that other suitable materials can be  
15 used. Also, while exemplary pharmacological agents are disclosed  
16 for maintaining a state of the ciliary body, it is understood that  
17 other agents can be used. Furthermore, while the skirt has been  
18 shown comprised of a two to four haptics, it is recognized that a  
19 single haptic or five or more haptics may be utilized. Moreover,  
20 while the restraining struts and shells have been described with  
21 respect to skirts comprising haptics, it will be appreciated that  
22 the restraining struts and shells can be used with a circular  
23 skirt, as described with respect to the preferred embodiments. It  
24 will therefore be appreciated by those skilled in the art that yet

- 1 other modifications could be made to the provided invention
- 2 without deviating from its spirit and scope as claimed.

RECORDED - INDEXED